.....

(Original Signature of Member)

108TH CONGRESS
2D SESSION

H. R. _____

To promote technological advancements that will dramatically reduce the timeframe for the development of new medical countermeasures to treat or prevent disease caused by infectious disease agents or toxins that, through natural processes or intentional introduction, may pose a significant risk to public health now or in the future.

IN THE HOUSE OF REPRESENTATIVES

Mr. TURNER of Texas (for himself, [see attached list of cosponsors]) introduced the following bill; which was referred to the Committee on _____

A BILL

To promote technological advancements that will dramatically reduce the timeframe for the development of new medical countermeasures to treat or prevent disease caused by infectious disease agents or toxins that, through natural processes or intentional introduction, may pose a significant risk to public health now or in the future.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Rapid Pathogen Identification to Delivery of Cures Act''.

SEC. 2. FINDINGS AND POLICY.

(a) FINDINGS.—The Congress finds as follows:

(1) The possibility exists today that terrorists or others who intend harm to United States forces deployed abroad or to the homeland will use techniques in biotechnology to enhance the transmissibility, stability, virulence, or host range of a biological agent, or to render existing diagnostic, therapeutic, and vaccine strategies or innate immune responses against a biological agent less effective.

(2) This possibility will likely grow over time as such techniques develop, improve, and spread as an inevitable result of biotechnology innovation.

(3) Natural processes can also lead to the emergence of previously unknown and harmful pathogens or render known pathogens resistant to existing diagnostic, therapeutic, or adaptive immune approaches.

(4) Long delays in developing new and effective responses to pathogens are typical. The discovery, development, and approval process for new drugs and vaccines typically requires 10 to 20 years and costs an average of $800 million. These constraints

reflect the long, costly research and development process, including the failure of most drug or vaccine candidates to demonstrate favorable characteristics in pre-clinical testing, as well as the expensive, time-consuming clinical trials required to prove the safety and effectiveness of new treatments.

(5) Congress has already authorized the abridgement of the long testing and approval process required to ensure safety and efficacy under the emergency conditions of a severe outbreak of a harmful pathogen. However, it will likely still take years for even an experimental treatment or vaccine to become available.

(6) There is no coordinated, focused research and development program or overall national strategy to achieve significant and dramatic reductions in the timeframe from the identification of a pathogen to the development and emergency approval for human use of reasonably safe and effective new biodefense medical countermeasures against a previously unknown or engineered pathogen or toxin.

(7) Even utilizing existing technologies, there is no organized capability in the public or private sector to rapidly screen drug candidates for potential therapeutic activity against pathogens, develop and

manufacture drug, biological, or medical device products, or test already approved treatments for efficacy against a previously unknown or engineered biological threat that puts our deployed armed forces or the homeland at risk.

(8) In the area of infectious disease in particular, private sector firms are abandoning all types of innovation and research and development in favor of investments in more profitable medical markets.

(9) Tremendous potential exists for benefits to health by concerted, targeted public-private investment to dramatically reduce the timeframe for the development of new countermeasures. The pharmaceutical and biotechnology industries are fundamentally innovative and are quick to integrate new technologies. Useful and important discoveries and technological advances will be rapidly absorbed by the private sector, leading to faster delivery of new medicines and reductions in the costs of drug development.

(b) POLICY.—The Congress hereby declares it to be the national policy of the United States to promote technological advancements that will dramatically reduce the timeframe for the development of new medical countermeasures to treat or prevent disease caused by infectious

disease agents or toxins that, through natural processes or intentional introduction, may pose a significant risk to public health now or in the future.

SEC. 3. RAPID BIODEFENSE COUNTERMEASURES DEVELOPMENT NATIONAL STRATEGY.

Title III of the Homeland Security Act of 2002 (6 U.S.C. 181 et seq.) (Public Law 107–296) is amended by inserting after section 304 the following section:

"SEC. 304A. RAPID BIODEFENSE COUNTERMEASURES DEVELOPMENT NATIONAL STRATEGY.

''(a) NATIONAL STRATEGY FOR SHORTENING THE MEDICAL COUNTERMEASURE DEVELOPMENT TIMEFRAME.—Not later than 180 days after the date of the enactment of the Rapid Pathogen Identification to Delivery of Cures Act, the Secretaries of Homeland Security, Health and Human Services, and Defense shall submit to Congress a report setting forth a strategy to achieve dramatic reductions in the timeframe from pathogen identification to the development and emergency approval for human use of reasonably safe and effective priority countermeasure against a novel or unknown pathogen or toxin.

''(b) ELEMENTS.—The report under subsection (a) shall include the following:

''(1) The identification of the technical impediments to reductions in the timeframe from pathogen

identification to priority countermeasure development and approval under emergency conditions.

''(2) The identification of the research, development, and technology needs and clinical research needs to address these impediments.

''(3) The identification of existing research and development efforts in Federal agencies, academia and industry that are addressing the needs identified in subsection (c)(2).

''(4) The identification of facilities, programs and resources that can be utilized to address these research, development, and technology needs and clinical research needs among—

''(A) Federal agencies;

''(B) colleges and universities;

''(C) not-for-profit institutions;

''(D) industry, including information technology, software, robotics, pharmaceutical and biotechnology companies and their consortia; and

''(E) foreign research and technological institutions.

''(5) A proposal for the establishment of a coordinated and integrated federal program to address

these research, development, and technology needs, including—

"(A) the application of Federal Government resources, including recommendations for the allocation and prioritization of Federal funds;

"(B) interagency management and coordination mechanisms;

"(C) the establishment of partnerships between private corporations and Federal agencies or Federally funded entities;

"(D) information and technology sharing and coordination mechanisms among public, private, academic, not-for-profit, and international institutions;

"(E) the use of incentives to promote private sector participation; and

"(F) the adjustment of Federal regulatory requirements to promote private sector innovation.

"(6) The identification of potential liability concerns stemming from distribution of rapidly-developed priority countermeasures under emergency conditions and a proposal for regulatory or legislative approaches to eliminating these concerns.

''(7) A proposal for managing the transfer of new technologies and associated intellectual property rights.

''(c) CONSIDERATIONS.—In developing the national strategy under subsection (a), the Secretaries shall consider—

''(1) the research, development, and technology needs and clinical research needs of the entire pathogen identification to priority countermeasures discovery, development, production, and approval process, including—

''(A) initial identification and characterization of a pathogen or toxin, including the identification of any genetic or other manipulations;

''(B) priority countermeasures discovery;

''(C) pre-clinical testing and evaluation of priority countermeasures;

''(D) safety and efficacy animal testing, including the needs for approval under emergency conditions and accelerated approval of new priority countermeasure under the final rule 'New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible' published in the Federal

Register on May 31, 2002 (67 Fed. Reg. 37988);

''(E) safety and efficacy human testing, including mechanisms for the conduct of clinical trials under emergency conditions;

''(F) research-scale and full production-scale manufacturing, including biologics manufacturing sciences; and

''(G) the approval of priority countermeasure under emergency conditions;

''(2) the potential importance of advanced technologies such as automation, computer modeling and simulation, bioinformatics, pharmacogenomics, and bioengineering techniques for manufacturing;

''(3) the availability of sufficient manufacturing capacity for priority countermeasures production to meet potential public demand under emergency conditions; and

''(4) the current state of national and international collaborative research networks and applications to facilitate and encourage the rapid and coordinated development and sharing of laboratory and clinical research planning and results.

''(d) AUTHORITY TO CONTRACT.—The Secretary of Homeland Security, after consultation with the Secre-

taries of Health and Human Services and Defense and the working group established under section 319F(a) of the Public Health Service Act, may contract with any one or more for-profit or non-profit firm or institution to conduct the necessary research and analysis needed to complete any one or more of the elements described in subsection (b) of the report required in this section, provided the considerations described in subsection (c) are met.

''(e) DEFINITIONS.—In this section:

''(1) The term 'emergency conditions' refers to a declaration of emergency under section 564 of the Federal Food, Drug, and Cosmetic Act.

''(2) The term 'pathogen identification' means the point in time in which a specific agent that can be reasonably assumed to be the cause of (or has the potential to be the cause of) an infectious disease or toxin-induced syndrome has been identified and partially or wholly characterized scientifically.

''(3) The term 'priority countermeasure' has the same meaning given such term in section 319F(h) of the Public Health Service Act.

''(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $10,000,000 for fiscal year 2005.''.

SEC. 4. CLINICAL RESEARCH UNDER EMERGENCY CONDITIONS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish a system for the rapid establishment of clinical research programs to examine the safety and efficacy of new or existing treatments for novel, unknown, or bioengineered pathogens or toxins. The Secretary shall also provide the means for rapid dissemination of results and recommendations to clinicians nationwide.

(b) EMERGENCY FUND.—A fund is authorized to be established for use, at the discretion of the Secretary, solely for the support of clinical research as described in subsection (a).

SEC. 5. INTERAGENCY WORKING GROUP.

Section 319F(a) of the Public Health Service Act, as amended by Public Law 107–188, is amended—

(1) by inserting ''the Secretary of Homeland Security,'' after ''in coordination with the'';

(2) by redesignating subparagraphs (D) through (L) as subparagraphs (E) through (M), respectively; and

(3) by inserting after subparagraph (C) the following subparagraph:

''(D) development of a national strategy to achieve dramatic reductions in the timeframe

from the identification of a pathogen to the development and approval for human use under emergency conditions of priority countermeasures against a novel, unknown, or engineered pathogen or toxin;''.

SEC. 6. DEVELOPING THE CAPABILITY FOR RAPID BIODEFENSE COUNTERMEASURE DEVELOPMENT.

(a) RESEARCH.—Section 319F(h)(1) of the Public Health Service Act, as amended by Public Law 107–188, is amended—

(1) in subparagraph (C), by striking ''and'' after the semicolon;

(2) by redesignating subparagraph (D) as subparagraph (E); and

(3) by inserting after subparagraph (C) the following subparagraph:

''(D) the development of a capability to rapidly identify, develop, produce, and approve for human use under emergency conditions priority countermeasures against a novel, unknown, or engineered pathogen or toxin; and''.

(b) RESEARCH AND DEVELOPMENT AT THE DEPARTMENT OF DEFENSE.—Section 1601(a) of the National Defense Authorization Act for Fiscal Year 2004 (Public

Law 108–136) is amended by adding at the end the following: ''The program shall also include research, development, and procurement to provide the Federal Government with the capability to rapidly identify, develop, produce, and approve for human use under emergency conditions priority countermeasures against a novel, unknown, or engineered pathogen or toxin, and for which no existing countermeasure has been determined to be safe or efficacious.''.

(c) RESEARCH AND DEVELOPMENT AT THE DEPARTMENT OF HOMELAND SECURITY.—Title III of the Homeland Security Act of 2002, as amended by section 3 of this Act, is amended by inserting after section 304A the following section:

''SEC. 304B. DEVELOPING THE CAPABILITY FOR RAPID BIODEFENSE COUNTERMEASURE DEVELOPMENT.

''The Secretary, in collaboration with the Secretaries of Defense and Health and Human Services, shall carry out a program for research, development, and procurement to provide the Federal Government with the capability to rapidly identify, develop, produce, and approve for human use under emergency conditions priority countermeasures against a novel, unknown, or engineered patho-

gen or toxin, and for which no existing countermeasure has been determined to be safe or efficacious.''.